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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,502	01/28/2004	Maryse Lafouasse	P06312US01 - PHI 1367	3477
27142	7590	07/21/2005	EXAMINER	
MCKEE, VOORHEES & SEASE, P.L.C. ATTN: PIONEER HI-BRED 801 GRAND AVENUE, SUITE 3200 DES MOINES, IA 50309-2721			KRUSE, DAVID H	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 07/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/766,502

Applicant(s)

LAFOUASSE, MARYSE

Examiner

David H. Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **STATUS OF THE APPLICATION**

1. This Office action is in response to the Amendment and Remarks filed on 19 May 2005.
2. The rejections under 35 U.S.C. § 112, second paragraph, and 35 U.S.C. § 101, double patenting are withdrawn in view of Applicant's amendments to the claims.
3. The rejection under 35 U.S.C. § 103(a) is withdrawn in view of the showing of common ownership at the time of the invention.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

5. Claims 1-10 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 17 February 2005. Applicant's arguments filed 19 May 2005 have been fully considered but they are not persuasive.

Applicant argues that the genus of F1 hybrids encompassed by Applicant's claims 1-10 are described in relation to the deposit which would provide to one of skill in the art the ability to determine the cells and/or chromosomes of inbred line PH0GC, which provide an identifying structural feature possessed by all members of the claimed genus, and that most of the cells in a corn inbred will have two essentially duplicate sets

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of ten chromosomes (page 6, 2<sup>nd</sup> paragraph of the Remarks). Applicant argues that when F1 hybrid seed is produced it will receive one complete set of chromosomes from the inbred parent, regardless of whether the inbred is used as the male or female parent of the F1 hybrid, and that the genus of F1 hybrid seed and plants encompassed by Applicant's claims 1-10 all share the common structural attribute of having a complete set of the unique chromosomes of PH0GC. Applicant further argues that it can be said that an F1 hybrid made with PH0GC comprises the unique chromosomes of inbred PH0GC and that this unique set of chromosomes can be characterized by molecular marker methods known to those of ordinary skill in the art (page 6, 4<sup>th</sup> paragraph of the Remarks). These arguments are not found to be fully persuasive. The fact is that the cytoplasmic genome of a plant is only inherited from the female parent. Applicant states that typically the genotypes of the breeding cross parents are not known in detail (page 7, 1<sup>st</sup> paragraph of the specification). Crossing the described inbred maize line PH0GC with a second inbred maize plant of close genetic lineage would not necessarily allow one of skill in the art to distinguish with certainty that PH0GC is one of the parent lines. See *Vas-Cath Inc. v. Mahurkar* 1991 (CAFC) 19 USPQ2d 1111, 1115, which teaches that the purpose of the written description is for the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent; and at the same time, of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.

Applicant argues that the set of chromosomes disclosed in the present application via the seed of inbred line PH0GC deposited by Applicant at the ATCC, and that this unique set of chromosomes can be characterized by molecular marker methods known to those of ordinary skill in the art, therefore, Applicant has provided guidance as to identifying characteristics of the genetic composition of the entire genus of hybrids claimed (page 6, 5<sup>th</sup> paragraph of the Remarks). This argument is not found to be persuasive because said deposit only describes inbred line PH0GC, it does not describe molecular markers or the genus of F1 progeny plants encompassed by the instant claims.

Applicant's argument as directed to *Enzo* is not found to be persuasive (page 6, 6<sup>th</sup> paragraph of the Remarks). In *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609 (CA FC 2002) at 1615, the U.S. Court of Appeals Federal Circuit remanded to the District Court to decide if the deposit of biological material by *Enzo* would adequately describe the invention as broadly claimed. At 1616, the court states that a description of what a material does, rather than what it is, usually does not suffice (for written description), and that the disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purported described.

Applicant argues that the unique set of chromosomes of inbred maize line PH0GC is an identifying structural characteristic present in Applicant's seed deposit of PH0GC, and that the SSR profile of PH0GC is obtainable from the deposit by one of ordinary skill in the art (page 7, 1<sup>st</sup> paragraph of the Remarks). This arguments is not found to be persuasive because the function of the claimed maize plant, specifically F1

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hybrid progeny is a consequence of the combination of the genome from PH0GC and the genome of the second parent line. Applicant states that typically neither the genotypes of the breeding cross parents nor the desired genotype to be selected is known in any detail, and that it is not known how the genotype would react with the environment. Applicant states that this genotype by environment interaction is an important, yet unpredictable, factor in plant breeding, and that a breeder of ordinary skill in the art cannot predict the genotype, how that genotype will interact with various climatic conditions or the resulting phenotypes of the developing lines, except perhaps in a very broad and general fashion (page 7, 1<sup>st</sup> paragraph of the Specification). This is the same issue addressed by Kevern.

Applicant argues that Kevern, at column 4, lines 41-46, is specifically discussing segregating F2 populations of seed, and that an F2 population is not the invention claimed in claims 1-10. Applicant argues that an F1 hybrid is not a segregating population as, rather the F1 hybrids of the present application are genetically stable because they are based on genetically stable inbred lines. Applicant argues that in order to accomplish the goal of developing maize hybrids it is necessary to identify genetically unique and stable inbred lines, such as the claimed invention, in order to produce the F1 hybrid seed, and that it is vital to conceptually understand that the cited section of Kevern is not describing the use of stable inbred lines to produce F1 hybrid seed. Applicant argues that an F1 hybrid seed will inherit the stable genetics of the inbred line used to produce it, but that Kevern is describing the development of a genetically segregating F2 population, which is distinct from genetically stable F1 hybrid

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seed. Applicants argue that the use of stable inbred lines, such as PH0GC, does allow for one of ordinary skill in the art to describe F1 hybrids produced from inbred line PH0GC (page 17, 3<sup>rd</sup> paragraph of the Remarks). These arguments are not found to be persuasive because, although Kevern is referring to F2 segregating populations at column 4, lines 47-50, Kevern states that typically neither the genotypes of the breeding cross parents nor the desired genotype to be selected is known in detail and that it is not known how the desired genotype would react to the environment at lines 51-54. This is the same statement Applicant makes on page 7 of the instant specification. This statement by Kevern applies not only to F2 progeny but also to F1 progeny. Table 4 of the instant application is directed to an F2 hybrid produced by crossing inbred PH0GC with PH16K and further crossing with PHK05xPH854 or PH437. Table 4 does not adequately describe the genus encompassed by the instant claims because each second inbred parent would produce a different and distinct F1 hybrid progeny. Applicant only describes, by way of a deposit of inbred PH0GC, a partial structure of the claimed genus of F1 hybrid maize plants. See *In re Wallach*, 71 USPQ2d 1939 (CA FC 2004), at 1940: Claims in application directed to isolated DNA molecules encoding proteins that inhibit cytotoxic effects of tumor necrosis factor were properly rejected for failure to satisfy written description requirement of 35 U.S.C. § 112, since applicants claimed nucleic acids encoding protein for which they provided only partial sequence, and without approximately 95 percent of amino acid sequence that applicants did not disclose, it cannot be held that DNA molecules claimed in application have been described, since applicants' contention that they were in physical possession of protein

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does not establish their knowledge of that protein's amino acid sequence or any of its other descriptive properties, even though amino acid sequence is inherent property of protein, and since application does not provide adequate functional description, in that, with only partial amino acid sequence disclosed, chemical structure of nucleic acid molecules that can serve function of encoding protein's amino acid sequence cannot be determined. In the instant case, Applicants only describe half of the claimed structure, wherein such a half structure cannot adequately describe the full structure and function of the claimed composition as broadly claimed. One of skill in the art cannot envision the structural and/or functional characteristics of the genus of F1 hybrid progeny of inbred PH0GC, only knowing such characteristics of inbred PH0GC.

6. Claims 1-10 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for inbred maize line PH0GC, deposited under ATCC Accession No. PTA-4523 and methods of using, does not reasonably provide enablement for a seed comprising at least one set of chromosomes of maize inbred line PH0GC as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is modified from the rejection of record as set forth in the last Office action mailed 17 February 2005. Applicant's arguments filed 19 May 2005 have been fully considered but they are not persuasive.

Applicant's arguments concerning the teachings of Kevern at pages 9-10 of the Remarks have been extensively addressed above.



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Applicant argues that Carlone is discussing the traits of the inbred (or parental) line. Applicant argues that the patent cited by the Examiner is one in which Carlone developed a novel inbred line and was allowed claims to the hybrid seed and plants produced from the novel inbred line, therefore, Applicant respectfully states the Examiner has misinterpreted the cited portion of the Carlone reference (paragraph spanning pages 10-11 of the Remarks). First, each application is examined upon its own merits. Second, the instant claims require the use, by one of skill in the art, of a second inbred parent maize plant. The teachings of Carlone is relevant to the instant rejection because it teaches that one of skill in the art would have to practice undue trial and error experimentation to cross the exemplified PH0GC inbred maize line with a myriad of other inbred maize lines to make useful F1 hybrids as broadly claimed.

Applicants argue that Segebart is discussing segregating F2 populations of seed; in contrast, the claimed invention teaches the use of stable and genetically fixed inbred lines to produce an F1 hybrid. Applicants argue that the claimed F1 hybrids are not from a segregating population but rather from a highly homogeneous, homozygous and reproducible inbred maize line PH0GC, and that an F1 hybrid is not the result of a segregating population but rather is the result of a superior, stable and genetically fixed inbred maize line that produces the claimed F1 hybrids (page 11, 3<sup>rd</sup> paragraph of the Remarks). These arguments are not found to be persuasive because Applicant teaches only one inbred parent of the claimed F1 hybrid maize plants. Applicant does not teach what number or combination of genes controlling useful characteristics of a maize plant are in inbred maize plant PH0GC. Segebart teaches that no line contains the favorable

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allele at all loci, and that different alleles have different economic values depending on the genetic background and field environment in which the hybrid is grown. Segebart also teaches that there are many genes affecting grain yield and that each of these has a relatively small effect on this trait. The fact that Segebart is discussing the development of inbred maize lines from segregating F2 populations does not obviate the teachings that one of skill in the art must practice trial and error experimentation in combining two inbred maize plants to determine what combination is useful.

Applicant argues that Segebart '109 is discussing segregating F2 populations of seed, but that in contrast, the claimed invention teaches the use of stable and genetically fixed inbred lines to produce an F1 hybrid. Applicant argues that the claimed F1 hybrids are not from a segregating population but rather from a highly homogeneous, homozygous and reproducible inbred maize line PH0GC (paragraph spanning pages 11-12 of the Remarks). This argument is addressed above.

Applicant argues that inbred maize lines are primarily used to produce F1 hybrid seed and plants, and that the claimed F1 hybrid seed is routinely and easily produced by crossing a plant from an inbred maize line PH0GC with a plant from another inbred maize line (page 12, 2<sup>nd</sup> paragraph of the Remarks). This argument is not found to be persuasive because given the teachings of the art, Applicant has failed to teach one of skill in the art at the time of the invention how to use F1 hybrids produced from inbred maize line PH0GC as broadly claimed.

Applicant argues that it is important to note that one of ordinary skill in the art would know that the pericarp tissue of inbred PH0GC is genetically identical to the

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maternal parent, and that it is well known to one of skill in the art that a maize seed is comprised of various types of tissue with different genetic composition. Applicant argues that the pericarp tissue that surrounds the seed is  $2n$  maternal tissue only, the embryo is  $2n$  tissue resulting from the fusion of one maternal and one paternal gamete, and the endosperm is  $3n$  tissue resulting from the fusion of two maternal and one paternal gametes. Applicant argues that the seed of maize has been described as a 'one-seeded fruit', where the ovary wall from the maternal parent is transformed into the tough outer pericarp that surrounds the kernel, therefore, Applicant points out that intact cells from inbred PH0GC will be a component of the F1 hybrid seed produced with PH0GC as the maternal parent. Applicant further argues that the genetic composition of the pericarp tissue of the F1 hybrid seed is an identifying structural feature present in the plants produced from the deposited seed of PH0GC and can be characterized by molecular markers (page 12, 4<sup>th</sup> paragraph of the Remarks). Although this appears to the Examiner to be an argument directed to written description, it is not found to be persuasive. The use of the seed produced from an inbred maize line lies in the plant produced therefrom, as in claims 2 and 3 of the instant application.

Given the breadth of the instant claims, it remains the Examiner's opinion that it would have required undue trial and error experimentation of make and use the genus of F1 hybrid progeny of inbred maize line PH0GC as broadly claimed. One of skill in the art at the time of the invention would understand that the intended use of F1 hybrid seed produced from an inbred maize line is to produce an F1 hybrid maize plant. See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC 112,

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first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."

### ***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. No claims are allowed.

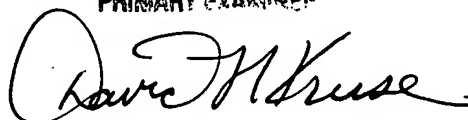
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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at (571) 272-0745. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.  
PRIMARY EXAMINER



David H. Kruse, Ph.D.  
13 July 2005

10. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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